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Original Article

Evaluation of short-and mid-term outcomes after endovascular treatment of long-segment femoropopliteal lesions

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Abstract

Aim: To evaluate short- and mid-term clinical, hemodynamic and functional outcomes of endovascular treatment (EVT) using directional atherectomy combined with drug-coated balloon (DCB) angioplasty in long-segment femoropopliteal artery disease and to identify predictors of restenosis.

Material and Methods: This retrospective, single-center study included 42 patients treated between January 2023 and December 2024 due to long-segment femoropopliteal occlusive disease. All patients underwent atherectomy followed by DCB angioplasty. Primary stenting was performed in 22 patients, while bailout stenting was required in 8 patients. All diagnoses were confirmed using pre-procedural computed tomography angiography (CTA). Follow-up was performed at 6 and 12 months using clinical evaluation and duplex ultrasonography (DUS). Restenosis was defined as >50% luminal narrowing or a peak systolic velocity (PSV) ratio of >2.5. Primary patency was analyzed using Kaplan–Meier survival analysis. Predictors of restenosis were evaluated using Cox proportional hazards regression.

Results: The primary patency rates were 81% at 6 months and 69% at 12 months. Walking distance significantly improved from 85 meters preoperatively to 500 meters at 12 months ($p<0.001$). Marked improvement was observed in Rutherford classification. Diabetes mellitus, smoking and hyperlipidemia were significant independent predictors of restenosis. Minor access-site complications occurred in 3 patients (7.1%), all of which resolved conservatively.

Conclusion: EVT provides favorable short- and mid-term outcomes in patients with long-segment femoropopliteal artery disease. Nevertheless, mid-term restenosis remains a major limitation. Comprehensive management of modifiable risk factors combined with the use of advanced endovascular devices is essential for improving long-term patency and clinical success.

Keywords: Femoropopliteal occlusion, endovascular therapy, restenosis, peripheral arterial disease, vascular intervention

INTRODUCTION

Peripheral arterial disease (PAD) is a major global health burden, particularly among the elderly and individuals with multiple cardiovascular comorbidities. It is closely associated with high morbidity and mortality rates [1,2]. One of the most prevalent forms of PAD is long-segment femoropopliteal artery disease (FPAD), characterized by stenotic or occlusive lesions in the lower extremity arteries, leading to symptoms such as intermittent claudication, rest pain, tissue necrosis, and limb loss in advanced cases [3–5].

The principal objectives of the treatment of femoropopliteal artery disease include relief of ischemic symptoms, improvement of functional capacity and quality of life, and prevention of limb amputation. Although open surgical revascularization has traditionally been considered the standard of care, advancements in endovascular therapy have shifted therapeutic preferences toward minimally invasive approaches [6,7]. Endovascular therapy offers reduced perioperative complication rates, shorter hospital stays, and faster recovery times [8,9].

However, the long-term durability of EVT in complex lesions,

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particularly TASC II types C and D long-segment occlusions, remains controversial. According to published studies, the 12-month primary patency rates for such lesions range between 60% and 75% [10,11]. Moreover, risk factors including diabetes mellitus and smoking significantly increase the likelihood of restenosis, thereby compromising procedural success [12].

The present study was designed to evaluate the short- and mid-term outcomes of EVT in patients with long-segment femoropopliteal occlusions, and to examine the impact of diabetes, smoking, and hyperlipidemia on vessel patency.

MATERIAL AND METHODS

Study Design and Ethics

This single-center, retrospective study included patients who underwent successful endovascular therapy (EVT) for long-segment femoropopliteal artery occlusion between 2023 and 2024. The study protocol complied with the principles of the Declaration of Helsinki and was approved by the local institutional ethics committee (Decision No 2024/10-16).

Patient Selection

This was a retrospective, single-center cohort study including 42 consecutive patients who underwent EVT for long-segment femoropopliteal artery disease between January 2023 and December 2024.

Inclusion Criteria

- TASC II type C or D femoropopliteal lesions
- Rutherford classification 4 or 5
- Age ≥18 years
- Minimum follow-up of 12 months

Exclusion Criteria

- Acute arterial thrombosis
- Previous surgical bypass of the target limb
- Active malignancy or systemic infection
- Severe renal dysfunction (eGFR <30 mL/min/1.73 m²)
- Inadequate follow-up data

The study protocol was approved by the institutional ethics committee.

Lesion and Anatomical Characteristics

Among the 42 patients:

- Total occlusion: 35 patients (83.3%)
- Near-occlusion: 7 patients (16.7%)

Calcification severity:

- Severe: 35 patients (83.3%)
- Moderate: 7 patients (16.7%)

Crossing technique:

- Intraluminal: 37 patients (88.1%)
- Subintimal: 5 patients (11.9%)

Distal runoff status:

- 32 patients (76.2%) had two-vessel runoff
- 10 patients (23.8%) had three-vessel runoff

Data Collection

Demographic information (age, sex), cardiovascular risk factors (smoking, diabetes mellitus, hypertension, and hyperlipidemia), comorbidities, and lesion-related parameters (lesion length and TASC II classification) were retrospectively obtained from the institutional electronic medical record system.

Endovascular Procedure

All procedures were performed under local anesthesia in a hybrid operating suite.

Standardized protocol:

1. Directional atherectomy using Jetstream™ or Uprooter™ systems in all patients.
2. Drug-coated balloon angioplasty in all lesions.
3. Primary stenting in 22 patients (52.4%) due to severe recoil or extensive calcification.
4. Bailout stenting in 8 patients (19.0%) due to flow-limiting dissection or residual stenosis of >30%.

No patient underwent plain balloon angioplasty alone.

Dual antiplatelet therapy was administered for at least 6 months post-procedure.

Imaging and Follow-up Protocol

All patients underwent pre-procedural CTA for diagnosis and treatment planning.

Post-procedural follow-up:

- Clinical evaluation in patients with palpable distal pulses
- Duplex ultrasound in patients with non-palpable pulses
- CTA in 2 patients with suspected restenosis or symptom recurrence

Restenosis criteria:

- Luminal narrowing >50%
- Or PSV ratio>2.5 on DUS

Follow-up visits were scheduled at 6 and 12 months.

Statistical Analysis

Data analysis was performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), and categorical variables were expressed as frequencies and percentages. The Kolmogorov–Smirnov test was used to assess data normality.

Group comparisons were made using Student's t-test for normally distributed variables, the Mann–Whitney U test for nonparametric data, and the Chi-square or Fisher's exact test for categorical variables.

Primary patency rates were calculated using the Kaplan–Meier method, and differences between groups were compared using the log-rank test. Multivariate analysis was performed using Cox proportional hazards model. Statistical significance was set at $P<0.05$.

RESULTS

Patient Demographics and Cardiovascular Risk Factors

A total of 42 patients met the inclusion criteria and were analyzed. The mean age of the study population was 62.4±9.8 years, with males comprising 92.9% of all cases. The most prevalent cardiovascular risk factor was cigarette smoking (71.4%), followed by hypertension (50.0%), hyperlipidemia (40.5%), and diabetes mellitus (28.6%) (Table 1). The mean lesion length was 18.3±4.7 cm.

Rutherford class changes demonstrated marked clinical improvement (Table 2).

Table 1. Baseline demographic, clinical and lesion characteristics

Variable	Value
Number of patients	42
Age (years)	62.4±9.8
Male sex	39 (92.9%)
Smoking	30 (71.4%)
Diabetes mellitus	12 (28.6%)
Hypertension	21 (50.0%)
Hyperlipidemia	17 (40.5%)
Total occlusion	35 (83.3%)
Near-occlusion	7 (16.7%)
Severe calcification	35 (83.3%)
Moderate calcification	7 (16.7%)
Intraluminal crossing	37 (88.1%)
Subintimal crossing	5 (11.9%)
Two-vessel runoff	32 (76.2%)
Three-vessel runoff	10 (23.8%)

Table 2. Clinical and functional outcomes

Parameter	Pre-procedure	12-month Follow-up
Walking distance (m)	85	500
Rutherford 1	0	22
Rutherford 2	0	14
Rutherford 3	0	6
Rutherford 4	36	0
Rutherford 5	6	0

Procedural Success and Complications

Technical success was achieved in all 42 procedures (100%), with no major perioperative complications, such as vessel rupture, distal embolization, or procedure-related mortality. Minor events, including transient groin hematoma or mild access-site bleeding, were self-limiting and resolved without further intervention (Table 3).

Table 3. Procedural complications

Parameter	n (%)
Minor complications	3 (7.1)
Access-site hematoma	3 (7.1)
Major complications	0
Limb loss	0

Primary Vessel Patency and Restenosis

According to Kaplan–Meier survival analysis, the primary vessel patency rates were 81.0% at 6 months and 69.0% at 12 months of follow-up (Table 4). Restenosis occurred most frequently in patients with diabetes mellitus, with a 12-month restenosis rate of 38.5%. The corresponding rates were 25.9% for smokers and 33.3% for those with hyperlipidemia.

Table 4. Primary patency and restenosis rates

Follow-up Time	Primary Patiency (%)	Restenosis (%)
6 Month	81.0	19.0
12 Month	69.0	31.0

Predictors of Restenosis

Multivariate Cox regression analysis identified three independent predictors of restenosis (Table 5).

- ***Diabetes mellitus:*** HR=2.41; 95% CI: 1.24–4.65; p=0.011
- ***Smoking:*** HR=1.89; 95% CI: 1.03–3.46; p=0.038
- ***Hyperlipidemia:*** HR=1.74; 95% CI: 1.02–3.15; p=0.022

Table 5. Cox regression analysis results

Risk Factor	HR (95%CI)	p-Value
Diabetes Mellitus	2.41 (1.24-4.65)	0.011
Smoking	1.89 (1.03-3.46)	0.038
Hyperlipidemia	1.74 (1.02-3.15)	0.022

Functional Outcomes

After EVT, 88% of the patients demonstrated a significant improvement in walking distance, and all patients experienced at least one grade reduction in Rutherford classification compared to baseline ($p<0.001$). No limb amputation cases were recorded during the follow-up period.

Table 6. Restenosis rates by risk factor

Risk Factor	Restenosis Rate	p-Value
Diabetes Mellitus	38.5%	0.011
Smoking	25.9%	0.038
Hyperlipidemia	33.3%	0.022

DISCUSSION

The present study evaluated the short- and mid-term outcomes of endovascular therapy (EVT) for long-segment femoropopliteal artery disease and examined the effects of key cardiovascular risk factors on restenosis.(Table 6).Our findings demonstrate that EVT yields high technical success and acceptable patency rates even in patients with complex TASC II type C and D lesions.

Previous reports have emphasized the limitations of EVT in long or heavily calcified femoropopliteal lesions, mainly because of higher restenosis rates [13,14]. Laird et al. [15] reported a 12-month primary patency rate of 72% with drug-coated balloon (DCB) therapy, whereas Kudo et al. [16] observed a 65% one-year patency rate following stent-supported interventions. The primary patency rates observed in our series (81% at six months and 69% at 12 months) are consistent with those of previous studies, suggesting that EVT provides durable short- and mid-term results when performed with contemporary devices and techniques.

Among the analyzed variables, diabetes mellitus emerged as the most significant predictor of restenosis. Structural vascular changes, endothelial dysfunction, and chronic inflammation associated with diabetes contribute to neointimal hyperplasia and luminal narrowing [9]. In our study, restenosis occurred in 38.5% of patients with diabetes, which aligns with the 35–40% rates reported in similar cohorts by Zeller et al. [4].

Smoking also had a notable negative impact on vascular outcomes. Cigarette exposure promotes oxidative stress, endothelial damage, and thrombotic activity, all of which can impair vessel healing after intervention [19]. Our results demonstrated a significant relationship between smoking and restenosis ($p = 0.038$), which is consistent with the findings of Schillinger et al. [20], who described comparable outcomes in a multicenter analysis.

Hyperlipidemia was another independent risk factor of restenosis in our cohort. Elevated lipid levels accelerate atherosclerotic plaque formation and vascular inflammation, which can compromise the long-term patency [21]. Therefore, aggressive lipid-lowering therapy may enhance outcomes following EVT in this patient population.

Although surgical revascularization remains the traditional gold standard for managing long-segment femoropopliteal occlusions [22], endovascular approaches have gained widespread acceptance, especially in elderly or high-risk surgical candidates [23]. The combination of drug-coated balloons, drug-eluting stents, and atherectomy systems allows for improved lesion preparation and better luminal outcomes, helping bridge the historical performance gap between EVT and bypass surgery [24].

Kılıç et al. [25] reported early and mid-term patency rates of 94% and 78%, respectively, after femoropopliteal bypass surgery, while Kolbakır et al. [26] observed rates of 80% and 60%. Considering these results, our findings indicate that with continued advancements in endovascular devices and operator experience, EVT outcomes are approaching those of surgical revascularization, particularly in terms of mid-term vessel patency and limb salvage.

The strengths of this study include its homogeneous patient population, standardized treatment protocol, and follow-up performed by an experienced vascular team. However, this study has several limitations.

Major limitations include:

- Small sample size
- Retrospective single-center design
- Predominantly male population
- Short follow-up duration
- Lack of device-specific outcome analysis

In summary, our data confirmed that EVT is an effective and reproducible treatment option for patients with long-segment femoropopliteal artery lesions. However, restenosis continues to pose a clinical challenge, highlighting the need for optimized risk factor control and adoption of advanced endovascular technologies to improve long-term outcomes.

CONCLUSION

Endovascular treatment combining atherectomy and drug-coated balloon angioplasty is a safe and effective minimally invasive

alternative for managing long-segment femoropopliteal artery occlusion. In the present study, the primary vessel patency rates of 81% at 6 months and 69% at 12 months support the procedural reliability and clinical efficacy of EVT in this challenging patient group.

Nevertheless, mid-term restenosis remains a major concern that limits its long-term durability. Modifiable cardiovascular risk factors, particularly diabetes mellitus, smoking, and hyperlipidemia, have been found to significantly increase the likelihood of restenosis. Therefore, beyond achieving technical success, the comprehensive management of these risk factors is crucial for sustaining vessel patency and improving functional outcomes.

Future studies with larger patient populations and longer follow-up durations are required to further validate these findings and explore advanced endovascular strategies aimed at enhancing long-term success.

Ethics Committee Approval: It was received from the İzmir Tepecik Training and Research Hospital Non-Interventional Research Ethics Committee, under the İzmir Provincial Directorate of Health (decision no: 2024/10-16) (04.12.2024).

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